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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,027	03/26/2002	William E. Jack	NEB-166-PUS	9409
28986	7590	11/04/2005		
HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC. 240 COUNTY ROAD IPSWICH, MA 01938-2723				

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,027

Applicant(s)

JACK ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 19-31 is/are rejected.
- 7) ☒ Claim(s) 13 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicants amendment of the specification (i.e. Sequence listing) and claims 6, 8-10, 13-18 and 23-26, in the paper of 8/17/2005 is acknowledged. Claims 1-31 remain pending and at issue for examination.

Information Disclosure Statement

Applicants filing of information disclosure statement filed on 12/10/2004, is acknowledged. Those references considered have been initialed.

Claim Objections

Claims 13, 18 objected to because of the following informalities:

Claims 13 and 18 are dependent on rejected claims 1-3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 11, 14-17 and 19-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applies to previous claims 1-7, 11, 14-17 and 19-31. In response to this rejection applicants have amended

claims 6, 8-10, 13-18 and 23-26 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that applicants have demonstrated that Family B DNA polymerases share conserved protein sequences in several regions, more particularly the exonuclease and active site motifs and that this similarity in composition leads to similarity in structure and function. Applicants further submit that applicants teach and describe the claimed method using four separate and distinct Family B DNA polymerases, namely Vent, Deep Vent, Pfu and 9°N, all derived from different organisms. In further support of the homology between Family B DNA polymerases, applicants submit that Table 1 shows that variants with analogous mutations from Family B polymerases have similar effects and that the Family B DNA polymerases have the same or similar pattern of nucleotide incorporation further evidencing that the claimed class of Family B DNA polymerases possess similar function and structure. Thus applicants conclude that given the description in the specification of the significant homology between Family B DNA polymerases, and the examples of four such Family B DNA polymerases, it would be apparent to the person of ordinary skill in the art that applicants were in possession of the claimed invention.

Applicants complete argument is acknowledged, however, found nonpersuasive on the basis that while applicants argue that they adequately describe the claimed methods of use of any Family B DNA polymerase, it remains that applicants claimed genus of methods is drawn to the use of any "Archaeon Family B DNA polymerase", and it remains if applicants have adequately described the claimed sub-genus, in light of

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applicants arguments directed to the genus (unclaimed). Applicants arguments are directed to a common structure shared by Family B DNA polymerases, however, it remains how this structure relates to the necessary limitation of the claimed methods that the "derivatized dideoxynucleotide is incorporated more efficiently than the corresponding underivatized dideoxynucleotide". This structure to function relationship remains unclear both with respect to those "archaeon Family B DNA polymerases" that have such a "function" as well as those "derivatized/underivatized dideoxynucleotides" that share such a relationship with a specific "archaeon Family B DNA polymerase". Given this lack description of the genus encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-12, 14-17 and 19-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method for site-specific incorporation of derivatized dideoxynucleotides, acyclonucleotides or derivatized acyclonucleotides into DNA comprising reacting a archaeon Family B DNA Polymerase, a primed DNA template and a nucleotide solution containing the referred to nucleotide to produce

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fragments of DNA with the referred to nucleotide covalently attached to the 3'-terminal residue, wherein said archaeon Family B DNA polymerase is Vent, Deep Vent, *Pfu* and 9oNTM or the specifically disclosed variants referred to in claim 18, does not reasonably provide enablement for any method for site-specific incorporation of derivatized dideoxynucleotides, acyclonucleotides or derivatized acyclonucleotides into DNA comprising reacting any archaeon Family B DNA Polymerase, a primed DNA template and nucleotide solution containing the referred to nucleotide to produce fragments of DNA with the referred to nucleotide covalently attached to the 3'-terminal residue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applies to previous claims 1-12, 14-17 and 19-31. In response to this rejection applicants have amended claims 6, 8-10, 13-18 and 23-26 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection, as the above rejection, under lack of written description, on the basis that applicants have demonstrated that Family B DNA polymerases share conserved protein sequences in several regions, more particularly the exonuclease and active site motifs and that this similarity in composition leads to similarity in structure and function. Applicants further submit that applicants teach and describe the claimed method using four separate and distinct Family B DNA polymerases, namely Vent, Deep Vent *Pfu* and 9°N, as well as variants thereof, that can

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be used in the claimed methods. In further support of the homology between Family B DNA polymerases, applicants submit that Table 3 shows the similarity of Region III of other Family B DNA polymerases. Applicants submit that Vent, Deep Vent Pfu and 9°N are not isolated and limited examples of the claimed method, but that these are merely representative members of the Family B DNA polymerases and one of skill in the art would be able to expect that one could practice the claimed methods with any Family B DNA polymerase.

Applicants complete argument is acknowledged, however, found nonpersuasive on the basis that, as discussed above, applicants claims remain so broad as to encompass any archaeon Family B DNA polymerase, and applicants have not sufficiently described this claimed genus of methods of use or the genus of archaeon Family B DNA polymerases or given sufficient guidance as to how one would obtain the necessary subgenus of DNA polymerases so as to provide guidance to one of ordinary skill in the art as to how to isolate any archaeon Family B DNA polymerase or guidance as to which of these archaeon DNA polymerases would be successful in the claimed method.

As above, Applicants arguments are directed to a common structure shared by Family B DNA polymerases, however, it remains how this structure relates to the necessary limitation of the claimed methods that the "derivatized dideoxynucleotide is incorporated more efficiently than the corresponding underivatized dideoxynucleotide". This structure to function relationship remains unclear both with respect to those "archaeon Family B DNA polymerases" that have such a "function" as well as those

“derivatized/underivatized dideoxynucleotides” that share such a relationship with each specific “archaeon Family B DNA polymerase”. Given this lack of description and guidance as to how to obtain the necessary polymerases of the genus encompassed by the claims, applicants have failed to sufficiently describe and enable the claimed invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to those archaeon DNA polymerases which must have the specifically discussed function (i.e. derivatized/underivatized dideoxynucleotides incorporation characteristic) necessary to practice the methods encompassed by the claims, including methods of use of all archaeon Family B DNA polymerase and variants thereof with such a functional characteristic.

The guidance argued by applicants (Tables 1 and 3) and provided by applicants, specification does not support the scope of the claims which encompass claimed methods of use of the recited archaeon Family B DNA polymerase. Because of this lack of guidance, it would require undue experimentation for one skilled in the art to arrive at the majority of those archaeon Family B DNA polymerases necessary to practice the methods of the claimed.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed methods of use of those archaeon Family B DNA polymerase with the specified derivatized/underivatized dideoxynucleotide incorporation characteristic. The scope of the claims must bear a

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reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
10/27/2005